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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,459	11/07/2001	David L. Lewis	Mirus.030.04	3774
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MIRUS CORPORATION 505 SOUTH ROSA RD MADISON, WI 53719				
EXAMINER				
GIBBS, TERRA C				
ART UNIT		PAPER NUMBER		
1635				
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03/21/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/007,459

Applicant(s)

LEWIS ET AL.

Examiner

TERRA C. GIBBS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 13-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 13-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission mailed on February 12, 2008 has been entered.

Claim 11 has been amended.

Claims 11 and 13-18 are pending in the instant application.

Claims 11 and 13-18 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Applicant's Amendment and Response filed February 12, 2008 have been considered. Rejections and/or objections not reiterated from the previous Office Action mailed October 9, 2007 are hereby withdrawn. Any arguments addressing said rejections and/or objections are moot. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Declaration filed under 37 C.F.R. §1.132

Applicant's Declaration filed under 37 C.F.R. §1.132 made of record on February 12, 2008 has been fully considered by the Examiner.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed October 9, 2007, claims 11 and 13-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmer, A. (Methods, 1999 Vol. 18:286-295, made of record in the previous Office Action mailed August 24, 2005) in view of Vaish et al. (Nucleic Acids Research, 1998 Vol. 26:5237-5242, made of record in the previous Office Action mailed July 25, 2006), and Zhang et al. (Human Gene Therapy, 1999 Vol. 10:1735-1737, made of record in the previous Office Action mailed August 24, 2005). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed October 9, 2007.

Response to Arguments

In response to this rejection, Applicants contend that the claims have been amended to recite that the volume of solution and the rate at which the solution is injected increases the volume of fluid within a vessel in the target tissue resulting in increased hydrostatic pressure against a wall of the vessel thereby increasing permeability of the vessel. Applicants have provided a Declaration filed under 37 C.F.R. §1.132 which primarily argues that Zimmer et al. teach an injection volume of 125 μ l, which is too small to cause an increase in hydrostatic pressure. Applicants

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contend that the inability to cause an increase in hydrostatic pressure would not be sufficient to cause an increase in vascular permeability within the vessel as recited in the instant claims. It is for these reasons that Applicants request reconsideration of the §103 rejection.

Applicant's arguments and contentions have been fully considered, and are found persuasive. Specifically, the Examiner has found the results contained within the Declaration filed under 37 C.F.R. §1.132 at page 4 to be persuasive. It is formally agreed that the injection volume of 125 μ l, taught by Zimmer et al. would not be enough to cause an increase in hydrostatic pressure sufficient to cause an increase in vascular permeability within the vessel as recited in the instant claims.

However, it has been dually noted that claim 11 has been amended to recite that the volume of solution and the rate at which the solution is injected increases the volume of fluid within a vessel in the target tissue resulting in increased hydrostatic pressure against a wall of the vessel thereby increasing permeability of the vessel is increased sufficient to cause an increase in vascular permeability within the vessel. Applicants, in their Remarks filed February 12, 2008 disclose that, "[H]ydrostatic pressure is pressure exerted by a fluid" (see page 3, second paragraph). It is also noted that the Declaration filed under 37 C.F.R. §1.132 discloses that an injection of 2.5 ml causes a great increase in intravascular hydrostatic pressure near the liver (see page 4 @ Graph). Given these disclosures, claims 11 and 13-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmer, A., in view of Vaish et al, and Zhang et al., for the reasons discussed as follows:

It should be noted that Zimmer et al. teach that it is important to focus on targeting colloidal drug carriers, such as antisense oligonucleotides, to the liver which could increase the efficacy of new drugs for hepatitis and liver cancer (see page 294 second column, first paragraph). The Examiner acknowledges that Zimmer et al. do not teach Applicant's claimed limitation that the volume of solution and the rate at which the solution is injected increases the volume of fluid within a vessel in the target tissue resulting in increased hydrostatic pressure against a wall of the vessel thereby increasing permeability of the vessel is increased sufficient to cause an increase in vascular permeability within the vessel.

Zhang et al. teach that the tail vein injection of naked plasmid DNA enables foreign gene expression in the liver (see Abstract). Zhang et al. also teach maximal gene expression in the liver was achieved when the DNA solution was injected within 7-120 seconds and at ~2.5 ml (see Figure 1, injection speed and injection volume, respectively). Zhang et al. conclude that the rapid and volumous injection of plasmid DNA has great potential for a wide variety of laboratory studies. It is noted that, based on Applicant's Remarks filed February 12, 2008 at page 3, second paragraph, and Applicant's Graph found in the Declaration filed under 37 C.F.R. §1.132, the Examiner is interpreting the rapid and high volume compositions injected via the tail vein taught by Zhang et al. to result in increasing hydrostatic pressure against a wall of a vessel which would subsequently result in increased permeability.

Therefore, while Applicant's Declaration filed under 37 C.F.R. §1.132 successfully showed that the 125 μ l volume taught by Zimmer et al. would be too small

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to increase hydrostatic pressure against a wall of a vessel, one of ordinary skill in the art would have been motivated to administer the antisense compositions of Zimmer et al. in a rapid and volumous injection via the tail vein because such methods have been identified as being highly favorable and successful for expression in the liver (see Zhang et al.).

Furthermore, Zimmer et al. teach the desire to target antisense drugs to the liver for the treatment of hepatitis. Zhang et al. teach an effective and easy method for delivering compositions to the liver, said method comprising rapid and high volume solutions administered via tail vein injections. Therefore, one of ordinary skill in the art would have been motivated to take the teachings of Zimmer et al. and combine them with the teachings of Zhang et al. to arrive at Applicant's claimed invention.

In view of the foregoing, when all the evidence is considered, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness made of record. Thus, it is maintained that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was filed.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

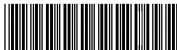
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

tcg
March 13, 2008

/Terra Cotta Gibbs/

Application Number**Application/Control No.**

10/007,459

**Applicant(s)/Patent under
Reexamination**

LEWIS ET AL.

Examiner

TERRA C. GIBBS

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